10/533835 JC06 Rec'a PCT/PTO 04 MAY 2005

### **EXPRESS MAIL CERTIFICATION UNDER 37 CFR 1.10**

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I hereby certify that the paper(s) identified above, and any document(s) referred to as attached hereto, is being deposited with the United States Postal Service on the date indicated in an envelope as "Express Mail Post Office to Addressee" and is addressed: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia, 22313-1450.

Christine Kotran

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

Markus Krumme

Serial No.

Filing Date

Herewith

Examiner

Group Art Unit:

Title

MULTILAYERED TRANSMUCOSAL THERAPEUTIC

SYSTEM (as amended herein)

Attorney File:

RO4037US (#90568)

#### INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 CFR 1.97

Mail Stop PCT Commissioner for Patents P O Box 1450 Alexandria, Virginia, 22313-1450

Dear Sir,

Under the provision of 37 C.F.R. 1.56, 1.97 and 1.98, Applicant would like to call the Examiner's attention to the references listed on the attached Form PTO-1449. Copies of the U.S. patent references are not enclosed. Copies of the non-U.S. patent references and non-patent references, all of which were cited in the International Search Report mailed April 6, 2004 in the prior international application PCT/EP03/12272, are also not enclosed.

In accordance with 37 C.R.F. 1.97(b)(1), and as this Information Disclosure Statement is being filed with the application, the Statement is submitted before the issuance of a first Official Action on this case.

In accordance with 37 C.F.R. 1.97(g) and 37C.F.R.1.97(h), filing of this

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Information disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 34 C.F.R. 1.56(b).

The Examiner is requested to make the attached references of record and to consider these references along with such other references deemed pertinent as a result of the Examiner's own independent search and examination.

Respectfully submitted,

D. Peter Hochberg Reg. No. 24,603

D. Peter Hochberg Co., L.P.A. 1940 E.6<sup>th</sup> Street – 6<sup>th</sup> Floor Cleveland, OH 44114-2294 (216) 771-3800 DPH/sfm

#### FORM PTO-1449

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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#### **U S PATENT DOCUMENTS**

Examiner Initial	Document Number	Date	Name			
	4,615,697	10/7/86	Robinson			
	4,713,243	12/15/87	Schiraldi, et al.			
	4,772,470	9/20/89	Horiuchi, et al.			
	4,855,142	8/8/89	Fankhauser, et al.			
	4,876,092	10/24/89	Mizobuchi, et al.			
	5,719,197	2/17/98	Kanios, et al.			
U.S. Published Applications						
Examiner	Document					
<u>Initial</u>	Number	Date	Name			
	2002/142036	10/3/2002	Rupprecht, et al.			

# JCCG Rec'd PCT/PTO 04 MAY 2005.

<u>Forei</u>	gn	Patent	<b>Documents</b>

Examiner	Document	10101511		Translation			
<u>Initial</u>	Number	Date	Country	(Yes/No)			
	WO 9955312	11/4/99	wo	No			
	EP 0275550	7/27/88	EPO	No			
	Other Prior Art (Inc. Author, Title, Date, Pertinent Pages, Etc)						
Examiner							
Initial	Docur	nent					
Cui, et al.; "Bilayer Films for Mucosal (Genetic) Immunization via the Buccal Route in Rabbits;" Pharmaceutical Research (New York); Vol. 19, No. 7, July, 2002; pages 947-953  Solomonidou, et al.; "Effect of Carbomer Concentration and Degree of Neutralization on the Mucoadhesive Properties of Polymer Films;" Journal of Biomaterials Science Polymer Edition; Vol. 12, No. 11 (2001), pages 1191-1205							
Examiner	Date Considered:						
Examiner:				not citation is in conformance			

Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant